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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NEW YORK, NY 10023

EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/10/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,407

Applicant(s)

PEER ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-64 is/are pending in the application.
- 4a) Of the above claim(s) 46, 48-53, 55 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-45, 47, 56-61, 63, and 64 is/are rejected.
- 7) ☒ Claim(s) 54 is/are objected to.
- 8) ☒ Claim(s) 33-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 1 Sheet
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

APPLICANTS' ARGUMENTS

Claims 33-64 (added) are acknowledged and claims 1-32 have been cancelled, as indicated by applicants in Paper No. 13, filed 20 April 2002. Claims 46, 48-53, 55 and 62 are withdrawn from consideration as not directed to the elected groups. Applicants' arguments in Paper No. 13, filed 20 April 2002, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

IMPROPER MULTIPLE DEPENDENT CLAIM

Claim 54 objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim. See M.P.E.P. § 608.01(n). Accordingly, the claim has not been further treated on the merits.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 33-45, 47, 56-61, 63 and 64.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 33-45, 47, 56-61, 63 and 64 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

LACK OF ENABLEMENT

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 33 (step (a)), 63 (step (a)), 64 (step (a)), and all claims dependent therefrom are not enabled and thus fails to provide guidance to practice, particularly "obtaining a probability $P_0(x)$ of the hybridization signal...and a probability $P_1(x)$ of the hybridization signal". Applicants' have failed indicate the steps to obtain the above probabilities; it is unclear how one would calculate the probabilities of hybridization. The specification (page 6, lines 16) indicates only the utilization of $P_0(x)$ and $P_1(x)$, however, does not provide guidance for one of skill in the

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art to obtain/derive said probabilities. The derivation steps of $P_0(x)$ and $P_1(x)$ of the hybridization signal is essential for the practice the claimed invention. The lack of steps/procedures/equations to obtain and calculate the above probabilities would not provide one skilled in the art sufficient guidance to perform and thus is unpredictable further requiring undue experimentation.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-45, 47, 56-61, 63 and 64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rejection is a reiteration from the previous office action, Paper No. 11, mailed 25 January 2002.

VAGUE AND INDEFINITE

Claims 33, 63, 64, and all claims dependent therefrom are vague and indefinite in that part (b) of claims 33, 63, and 64 "assigns a score to each of a plurality of candidate nucleotide sequences...based on the probabilistic spectrum and...one reference nucleotide sequence" but confusingly without indicating what the scoring algorithm is which calculates spectrum + sequence. Since the specification is believed to specify scoring algorithms, the claim is not commensurate in scope with the specification because of the unspecific claim versus the non-commensurate specification.

OBJECTION OF DISCLOSURE

The disclosure is objected to because of the following informalities:

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In particular, because the disclosure contains an embedded hyperlink and/or other forms of browser-executable code on page 2, paragraph 5. Applicants' amendment in Paper No. 13, filed 20 April 2002, of the specification failed to remove the hyperlink objection. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. § 608.01 and § 608.01(p). The current format utilized by applicants is executable, therefore, a suggested reference format for the said hyperlink objection is "World Wide Web address: ncbi.nlm.nih.gov/SNP/".

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *September 4, 2002*

Examiner Initials: *CSM*



MICHAEL P. WOODWARD
SUPERVISOR
TECHNOLOGY CENTER 1600